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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,933	11/01/2001	Jeong S. Lee	ACSC 60355 (2750)	5440
7590 05/05/2004				
GUNTHER O. HANKE, ESQ. FULWIDER PATTON LEE & UTECH , LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045			EXAMINER MCKANE, ELIZABETH L	
			ART UNIT 1744	PAPER NUMBER

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,933	Applicant(s) LEE ET AL.	
	Examiner Leigh McKane	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-12,14-24 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,7-12,21-24 and 26 is/are allowed.
- 6) ☒ Claim(s) 14,15 and 27-33 is/are rejected.
- 7) ☒ Claim(s) 16-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 15, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (U.S. Patent No. 5,849,846) in view of Sun et al (U.S. Patent No. 5,728,748).

Chen et al teaches a method of sterilizing a medical device component wherein the component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an electron beam (col.9, lines 21-45) so as to increase the burst strength, fatigue strength, and burst (i.e. rupture) pressure. *Note: As Chen teaches that the burst pressure (i.e. rupture pressure) is increased, then the second rupture pressure is not significantly less than the first rupture pressure. Chen et al is silent as to whether the e-beam radiation sterilizes the component. However, Sun et al teaches that e-beam radiation is effective in sterilizing polymeric materials. As the component of Chen et al will have to eventually undergo sterilization before use and since it is fabricated from a polymeric material like the components of Sun et al, one of ordinary skill in the art would have found it obvious to use the e-beam sterilization of Chen et al to both improve the performance characteristics of the component and to sterilize the component.

Although Chen et al does not disclose treating the component within a sealed, evacuated container, Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert

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gas. As Sun et al discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al. See col.4, lines 58-65).

3. Claims 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al in view of Sun et al as applied to claim 27 above, and further in view of Avellanet (U.S. Patent No. 5,733,496).

Chen et al teaches the application of electron beam radiation to polymeric catheter balloons but does not teach balloons made of the instant materials. However, Avellanet teaches irradiating catheter balloons made of polyether block amide (PEBAX) and PTFE. See col.3, lines 10 and 17; lines 46-48. As these materials are known both to be used in catheter balloons and to be capable of being irradiated, it would have been obvious to one of ordinary skill in the art to apply the method of Chen et al with Sun et al to catheter balloons made of PEBAX or PTFE.

4. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al in view of Sun et al, Avellanet, and Lafont et al (U.S. Patent No. 5,957,975).

Chen et al teaches a method of sterilizing a medical device component wherein the component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an electron beam (col.9, lines 21-45) so as to increase the burst strength, fatigue strength, and burst (i.e. rupture) pressure. *Note: As Chen teaches that the burst pressure (i.e. rupture pressure) is increased, then the second rupture pressure is equal to or not significantly less than the first rupture pressure. Chen et al is silent as to whether the e-beam radiation sterilizes the component. However, Sun et al teaches that e-beam radiation is effective in sterilizing polymeric materials.

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As the component of Chen et al will have to eventually undergo sterilization before use and since it is fabricated from a polymeric material like the components of Sun et al, one of ordinary skill in the art would have found it obvious to use the e-beam sterilization of Chen et al to both improve the performance characteristics of the component and to sterilize the component.

Although Chen et al does not disclose treating the component within a sealed, evacuated container, Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert gas. As Sun et al discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al. See col.4, lines 58-65).

Chen et al teaches the application of electron beam radiation to polymeric catheter balloons but does not teach balloons made of the instant materials. However, Avellanet teaches irradiating catheter balloons made of polyether block amide (PEBAX) and PTFE. See col.3, lines 10 and 17; lines 46-48. As these materials are known both to be used in catheter balloons and to be capable of being irradiated, it would have been obvious to one of ordinary skill in the art to apply the method of Chen et al with Sun et al to catheter balloons made of PEBAX or PTFE.

Chen et al with Sun et al fails to disclose that the balloon catheter is a stent delivery balloon catheter. However, Lafont et al teaches a stent delivery balloon catheter comprising an elongated shaft, a balloon mounted on the shaft, wherein the entire system can be sterilized with electron beam. See col.8, lines 39-45. Therefore, it would have been obvious to employ the method of the combination to sterilize assembled stent delivery systems. As to the limitation

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requiring that "sections of the balloon located directly underneath the stent are penetrated less by the electron beam than are sections of the balloon located at spaces in a wall of the stent," this is an inherent occurrence of radiation sterilization, as the balloon will be shadowed by the stent.

5. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafont et al in view of Sun et al.

Lafont et al teaches a method of sterilizing a balloon catheter wherein a stent is mounted on an outer surface of a balloon of a balloon catheter and the entire assembly is sterilized with electron beam radiation. See col.8, lines 39-45. Lafont et al does not disclose purging a container with the catheter therein and filling the container with an inert gas. Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert gas. As Sun et al discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Lafont et al. As to the limitation that "the stent reduces penetration of the electron beam into sections of the balloon located directly underneath the stent," this is a necessary result of radiation sterilization.

Allowable Subject Matter

6. Claims 1-12, 21-24, and 26 are allowed.

7. Claims 16-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 4 March 2004 have been fully considered but they are not persuasive.
9. On page 9, applicant argues that since Chen et al discloses that irradiating the catheter balloon increases the burst pressure and fatigue strength of the balloon, then the method of Chen et al does not render obvious the instant claims which require that the second rupture pressure be "equal to or not significantly less than the first rupture pressure." However, if the rupture pressure is increased, as it is in the method of Chen et al, then it is "not significantly less than the first rupture pressure."
10. As to the combination of Chen et al with Sun et al, the motivation to combine the two references has been given in the rejection above. Applicant's arguments that the oxidative degradation avoided by Sun et al is the equivalent of the radiation-induced toughening desired by Chen et al have no foundation in the prior art of record.
11. With respect to the arguments concerning Avellanet, the Examiner submits that if it is known to irradiate a catheter shaft made of PEBAX or PTFE, it would have been obvious to irradiate a balloon formed of the same material.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leigh McKane
Primary Examiner
Art Unit 1744

elm
3 May 2004